Supreme Court, U.S.
FILED
DEC 18 2001
CLERK

(4)

No. 01-441

In the Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

SUPPLEMENTAL BRIEF FOR THE RESPONDENT IN OPPOSITION

RUTH G. MALINAS
Ball & Weed, P.C.
745 E. Mulberry, Ste. 500
San Antonio, Texas 78212
(210) 731-6300

KENNETH S. GELLER
Counsel of Record
DAVID M. GOSSETT
Mayer, Brown & Platt
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

Counsel for Respondent

42pp

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES.....ii

CONCLUSION 3

TABLE OF AUTHORITIES

Page(s)

CASES

Brooks v. *Howmedica, Inc.*, No. 00-1188, __ F.3d __, 2001 WL 1568430 (8th Cir. Dec. 11, 2001) 1, 2, 3

Goodlin v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) 2

Medtronic, Inc. v. *Lohr*, 518 U.S. 470 (1996) 1, 2

Oja v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) 2

STATUTES AND RULES

Food Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* 1

Medical Device Amendments, 21 U.S.C. § 360c *et seq.* 1, 2

21 U.S.C. § 360k 1

S. Ct. R. 15.8 1

SUPPLEMENTAL BRIEF FOR THE RESPONDENT IN OPPOSITION

Pursuant to Rule 15.8 of the Rules of this Court, respondent submits this supplemental brief to draw the Court's attention to the Eighth Circuit's en banc decision in *Brooks* v. *Howmedica, Inc.*, No. 00-1188, __ F.3d __, 2001 WL 1568430 (Dec. 11, 2001), which we had noted (at Br. in Opp. 16) was pending, and which is attached as an appendix to this brief.

As we explained in our brief in opposition, there is no "'deep post-*Lohr* split in authority'" (Br. in Opp. 16, quoting Pet. 14) about the preemptive effect of the FDA's grant of premarket approval (PMA). By a 7-2 vote, the en banc Eighth Circuit has now found state law failure-to-warn claims preempted by the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, where a device had been reviewed by the FDA pursuant to the PMA process. Thus, yet another court of appeals has now explicitly held, as did the court below, that state law claims that would impose requirements "different from, or in addition to" those imposed by federal law (21 U.S.C. § 360k(a)) are preempted by the PMA process. The *Brooks* decision further undermines petitioners' claim that this case warrants the Court's review.

The *Brooks* court discussed (at App 5a-9a) the detailed and repeated review the FDA gives to a device's labeling. It noted that, under *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996),

> [t]he key question before the court is whether the specific state requirement [the plaintiff] wishes to impose on [the device] would interfere with a specific federal requirement, [which] question may also

> be phrased as whether the specific state and federal requirements conflict.

App 16a. Explaining that, under the PMA process, "[t]he FDA drafted or approved every word of the [device's] label, and any changes were subject to close FDA scrutiny" (App. 17a), the Eighth Circuit found that state law failure to warn claims were preempted under the MDA:

> The failure to warn claim asserted by [the plaintiff] would interfere or conflict with the specific federal requirements imposed during the regulation of [the device]. A jury finding of negligent failure to warn would be premised on the fact that the label for [the device] was not written in a particular way or did not contain certain information. This would be equivalent to a state regulation imposing specific label requirements.

App. 19a. See also *id.* at 23a ("Through its approval of the PMA application * * * and its continuing series of directives, the agency imposed specific federal requirements on Howmedica."). The same is true here. See Br. in Opp. 5-10.

The *Brooks* court also discussed and dismissed the two federal court of appeals decisions that petitioners rely upon to argue for review here. The Eighth Circuit distinguished *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) — as we did in our brief in opposition (at 20-21) — as a "case [that] involved approval through an investigational device exemption, a considerably less rigorous process than the full PMA" (see App. 18a, Pet. 20). It further explained (compare Br. in Opp. 18-19) that the "*Goodlin* [v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999)] court implied * * * that it would find preemption in a case involving an 'ascertainable requirement in an express FDA' order or regulation." (App. 18a (quoting *Goodlin*, 167 F.3d at 1375 (further citations omitted))).

Thus, as we noted in our brief in opposition, (at 17) "the great weight of authority — and all recent authority — favors

the Fifth Circuit's position" in the case under review, and there is no reason for the Court to grant the petition. The Eighth Circuit's *en banc* decision in *Brooks* confirms our submission that this issue does not warrant the Court's attention at the present time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

RUTH G. MALINAS
Ball & Weed, P.C.
745 E. Mulberry, Ste. 500
San Antonio, Texas 78212
(210) 731-6300

KENNETH S. GELLER
Counsel of Record
DAVID M. GOSSETT
Mayer, Brown & Platt
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

DECEMBER 2001